REMARKS

Claims 61-83 and 86 are pending . Claims 70-74, 76, and 78 are amended herein. No new matter is added by these amendments, support therefore being found throughout the application as filed.

1. 35 U.S.C. §103 Rejections

Pless and Diederich

Claims 61-63 and 84 are rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,811,562 to Pless (hereinafter "Pless") and U.S. Patent No. 6,177,101 to Diederich et al. (hereinafter "Diederich"). Applicants respectfully traverse.

The Office asserts that evidentiary submissions filed in connection with the prosecution of the Pless patent show that the subject matter of Pless was in the possession of Pless prior to the filing date of Applicants' provisional application (July 11, 2000). Applicants note that in Applicants' provisional application filing, it is indicated that the present invention was documented in the laboratory notebooks of the present inventors from March-June 2000.

Applicants provide a non-thermal method for treating and/or curing cardiac arrhythmias by administering a photosensitizing agent to at least one pulmonary vein, inserting an illumination device into the at least one pulmonary vein ostia and delivering illumination to activate the photosensitizing agent in the pulmonary vein, thereby ablating a section of the pulmonary vein and electrically isolating the pulmonary vein from the left atrium. As set out, Applicants' illumination device comprises a fiberoptic housed within a balloon, and the method involves inflating the balloon to achieve circumferential ostial contact in the pulmonary vein ostia and delivering illumination from the fiberoptic through the balloon.

As set forth in the present application, by placing an angioplasty type balloon about the fiberoptic, the fiberoptic catheter delivers illumination in annular/ring shaped pattern within the pulmonary vein.

Pless describes a device and method for creating lesions in cardiac tissue using photodynamic therapy. Pless's device is a generally linear member having a distal region with an axis, wherein the distal region includes a linear light emitting region corresponding to the axis (col. 8, lines 9-12). In particular, the device is provided with an elongated generally linear window 206 at its distal end through which light is transmitted and an opaque back side of the window that prevents light from being transmitted (see, e.g. col. 10. lines 33-38; Figs. 3A-5). The light emitting region is bendable to conform to curved cardiac tissue so that it can be placed exterior the heart to illuminate the heart surface (see Figs. 6-7). In particular, the device can be is placed so as to encircle the vein bed or veins (see col. 11, lines 15-24). In certain embodiments, the device is used to deliver light to the inside of the heart. As set forth, the design of the device is generally the same with a flexible body 306 extending to a distal linear window 308, and wherein the back side of the window is opaque to prevent light from being transmitted through that side of the device (see col. 10, line 61 – col. 11, line 3). Such a device could advantageously be used to provide interior linear lesions as shown, for example, in Fig. 1 which describes a "maze" procedure.

Thus, Pless specifies a device wherein a linear window is formed along one side of the device through which light is delivered and wherein the opposite side of the window is opaque to prevent light from being delivered therethrough. This design is specific for forming linear lesions along one linear side or face of the device while preventing delivery of light through other sides or faces of the device.

Nowhere does Pless teach or suggest a method wherein an illumination device is inserted within the pulmonary vein ostia and illumination is delivered to the inner surface of the pulmonary vein ostia to electrically isolate the pulmonary vein from the left atrium. Rather, according to Pless's method, the device is provided with the elongate window wrapped about the vein bed or veins so as to deliver light about the vein or vein bed outer surfaces. Further, when used to deliver light to the interior of the heart, Pless's device which has a longitudinally extending window through which light is transmitted is not designed for insertion within the pulmonary vein ostia in such a way that it would or could deliver illumination to the inner surface of the pulmonary vein ostia to electrically isolate it from the left atrium. Further,

nowhere does Pless teach or suggest a method wherein an illumination device comprising a fiberoptic housed within a balloon is inserted within the pulmonary vein ostia, the balloon inflated to achieve circumferential ostial contact in the pulmonary vein ostia, and illumination delivered from the fiberoptic through the balloon and to the inner surface of the pulmonary vein ostia to electrically isolate the pulmonary vein from the left atrium.

Further, it is respectfully submitted that one of skill in the art would not have modified Pless in view of Diederich as proposed by the Office. In particular, Pless provides a specific device design that provides an elongate linear illumination pattern along a single face of the device. This is done to prevent delivery of illumination from other faces of the device. Pless also describes specific placement of the device which requires this device design. Applicants respectfully submit that there is no teaching, suggestion, or motivation to modify the device and method of Pless to provide a balloon at the distal end of Pless's device or to provide Pless's device within the pulmonary vein ostia to deliver illumination. Rather, Pless is specific to the formation of elongate longitudinal illumination patterns, which would not be desirable or even suitable illumination patterns within the pulmonary vein ostia. It is respectfully submitted that the Office's proposed modification of Pless would require a substantial reconstruction and redesign of the elements shown in Pless as well as a change in the basic principle under which the Pless device was designed to operate.

Thus, claim 61 is patentable over Pless and Diederich. Claims 62, 63, and 84 depend from claim 61 and, thus, also are patentable over Pless and Diederich. Reconsideration and withdrawal of the rejection is respectfully requested.

Pless, Diederich, and Leone

Claims 64-67, 69-78, and 86 are rejected under 35 U.S.C. §103(a) over Pless, Diederich, and U.S. Patent No. 5,709,653 to Leone (hereinafter "Leone"). Applicants respectfully traverse.

For the reasons set forth above, claim 63 is patentable over Pless and Deiderich. Leone does not remedy these deficiencies. Leone is cited for allegedly describing the delivery of photosensitizer through a porous balloon. Applicants respectfully submit that for the same

reasons provided above, there is no teaching or suggestion to modify Pless as required by Applicants' claims and, as such, Applicants invention would still not be taught or suggested by the proposed combination of Pless, Diederich, and Leone.

Thus, claim 61 is patentable over Pless, Diederich, and Leone. Claims 64-67, 69-78, and 86 depend from claim 61 and, thus, also are patentable over Pless, Diederich, and Leone. Reconsideration and withdrawal of the rejection is respectfully requested.

Pless, Diederich, and Swanson

Claims 79-82 are rejected under 35 U.S.C. §103(a) over Pless, Diederich, and U.S. Patent No. 6,023,638 to Swanson (hereinafter "Swanson"). Applicants respectfully traverse.

For the reasons set forth above, claim 63 is patentable over Pless and Deiderich. Swanson does not remedy these deficiencies. Swanson is cited for allegedly describing the delivery of saline or anticoagulant as well as the use of a guidance technique such as MRI. Applicants respectfully submit that for the same reasons provided above, there is no teaching or suggestion to modify Pless as required by Applicants' claims and, as such, Applicants invention would still not be taught or suggested by the proposed combination of Pless, Diederich, and Swanson.

Thus, claim 61 is patentable over Pless, Diederich, and Swanson. Claims 79-82 depend from claim 61 and, thus, also are patentable over Pless, Diederich, and Swanson. Reconsideration and withdrawal of the rejection is respectfully requested.

Pless, Diederich, and Rice

Claim 83 is rejected under 35 U.S.C. §103(a) over Pless, Diederich, and U.S. Patent No. 6,200,309 to Rice (hereinafter "Rice"). Applicants respectfully traverse.

For the reasons set forth above, claim 63 is patentable over Pless and Deiderich. Rice does not remedy these deficiencies. Rice is cited for allegedly describing the use of phthalocyanines as photosensitizers. Applicants respectfully submit that for the same reasons

provided above, there is no teaching or suggestion to modify Pless as required by Applicants' claims and, as such, Applicants invention would still not be taught or suggested by the proposed combination of Pless, Diederich, and Rice.

Thus, claim 61 is patentable over Pless, Diederich, and Rice. Claim 83 depends from claim 61 and, thus, also are patentable over Pless, Diederich, and Rice. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicant respectfully requests early consideration and allowance of the subject application.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105.**

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

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Respectfully submitted,

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